K062611

PREMARKET NOTIFICATION

SEP 2 0 2006

510(k) SUMMARY

1.	Applicant:	Medical Intelligence Medizintechnik GmbH
2.	Address:	Feyerabendstrasse 13 – 15 86830 Schwabmünchen Germany
3.	Contact Person:	Christian Hieronimi Tel. +49 (0) 8232 9692-0
4.	Preparation Date:	February 15, 2006
5.	Device Submitted:	iGUIDE® System
6.	Proprietary Name:	iGUIDE® System
7.	Common Name:	iGUIDE
8.	Classification Name:	Medical charged-particle radiation therapy Product Code IYE
9.	Substantial Equivalence:	The iGUIDE® System is substantially equivalent to the following legally marketed devices: BrainLab "ExacTrac system" (K003285). The characteristics of this device are similar to those of the predicate devices identified on the comparison chart, which is provided with the premarket notification submission. It is our opinion that the iGUIDE® System does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.
10.	Device Description:	The iGUIDE® System controls the movement of the Medical Intelligence HexaPOD™ RT CouchTop (K041448), a radiographic treatment table with 6 DOFs (Degrees of freedom). With the integrated 3D Tracking System the device controls also the accuracy of the patient positioning. The iGUIDE® System consists of a PC workstation, a graphics user interface to the treatment table (software) and the NDI Polaris 3D Tracking System. The iGUIDE® System is integrated into radiation therapy systems of Elekta, Varian, and Siemens and is connected to them with an Interlock connection.
11.	Intended Use:	The intended use of the device is to control the movement and aid in positioning a patient during radiation therapy.
12.	Biocompatibility:	No patient contact – medical software
13.	Performance Data:	No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation).

Description:

The iGUIDE system is a powered radiation therapy support assembly.

The iGUIDE system controls the movement of the Medical Intelligence HexaPOD RT CouchTop (K041448), a radiographic treatment table with 6 DOFs (Degrees of Freedom). With the integrated 3D Tracking System the device controls also the accuracy of the patient positioning.

The iGUIDE system consists of a PC workstation, a graphics user interface th the treatment table (software) and the NDI Polaris 3D Tracking System.

The iGUIDE system is integrated into radiation therapy systems of Elekta, Varian and Siemens and is connected to them with an Interlock connection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 20 2006

Medical Intelligence Medizintechnik GmbH
c/o Mr. Stefan Preiss
Responsible Third Party Official
TÜV America Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K062611
Trade/Device Name: iGuide System
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: August 31, 2006
Received: September 5, 2006

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062611

Device Name: iGUIDE system

Indications For Use: The intended use of the device is the control of accurate patient positioning with assistance of a 3D Tracking System in a radiotherapy environment.

Prescription Use ✓ Yes
(Part 21 CFR 801 Subpart D)

~~AND~~/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF ~~NEEDED~~)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Jeyron

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062611